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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,298	06/12/2000	DIETER LUBDA	MERCK2047	2130
7590 12/08/2003 MILLEN WHITE ZELANO & BRANIGAN ARLINGTON COURTHOUSE PLAZA I 2200 CLARENDON BOULEVARD SUITE 1400 ARLINGTON, VA 22201			EXAMINER CHANG, VICTOR S	
			ART UNIT 1771	PAPER NUMBER

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/446,298

Applicant(s)

LUBDA ET AL.

Examiner

Victor S Chang

Art Unit

1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-15,17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The Examiner has carefully considered Applicant's amendments and remarks filed on 10/6/2003. Applicant's amendment to add new claims 18 and 19 has been entered. However, it is noted that claims 3, 5-15 and 17 are previously withdrawn, and as such should not be listed as "(Previously presented)", although no harm is seen to have occurred from this minor informality. Appropriate correction is required.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejections not maintained are withdrawn.

### ***Election/Restrictions***

4. With regard to Applicant's traversal of the restriction requirement (Remarks, page 6), the Examiner believes that he has fully established the propriety of the prior restriction requirement and has made the restriction requirement Final in Paper No. 19. Therefore, if Applicant wishes to further pursue the traversal of the restriction requirement, it is suggested that a petition is the appropriate course of action.
5. Newly submitted claim 19 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

It is noted that the newly added claim 19 recites "the pressure-resistant plastic casing contains glass or carbon fiber reinforcement", which is clearly directed to a

distinct species which is different from the originally presented species of PEEK or PTFE.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 19 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Response to Amendment***

6. Claims 1, 2, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/19687 either taken individually, or in view of FR 2654835A (Derwent Abstract), substantially for the reasons set forth in section 5 of Paper No. 19, together with the following additional observations.

The two newly filed Declarations dated 10/6/2003 by Drs. Harders and Lubda have been carefully considered. However, in the absence of a comparable thickness of the sleeve of the instant invention, the Declarations still appear to be unsupported by objective factual evidence, and do not remedy the prior deficiency that the Declaration dated 2/13/2003 fails to show the results as a valid comparative study. See MPEP § 716.01(c).

With respect to Applicants' argument that "including the Matsushita '538 patent ... The new Declaration supplements the previous one, attesting that the thickness of Teflon sleeve in the previous experiments was 0.15 mm." (Remarks, page 7, first

paragraph), the Examiner must first note that the Matsushita '538 reference has not been relied upon in the prior Office Action of Paper No. 19. As to the thickness of Teflon sleeve, although it is now disclosed in the new Declaration dated 10/8/2003 by Dr. Lubda, the Declarations are still deficient as set forth above. Further, even if the thickness of the sleeve of the instant invention is disclosed, the Examiner repeats (see Paper No. 19, page 3) that FR '835 is directed to a high pressure liquid chromatography column, and FR '835 also expressly teaches that "The thickness of the wall is not critical" (see Declaration dated 10/6/2003 by Dr. Harders, page 5, last two lines). As such, it is believed that a suitable thickness of the sleeve for high pressure chromatography column is either inherently disclosed, or an obvious optimization to one of ordinary skill in the art of making high pressure chromatography column, motivated by the desire to obtain a chromatography column which is able to operate in the required range of high pressures, as suggested by FR '835.

With respect to Applicants' argument that "WO '687 requires an outer pressure-resistant covering ... makes evident that the Teflon sleeve is not pressure resistant" (Remarks, page 7, first paragraph), the Examiner notes that even if the WO '687 uses a thin Teflon sleeve, it should be noted that Applicants have acknowledged that WO '687, as a whole, teaches that an outer covering is incorporated to provide required pressure resistance. As such, WO '687 in fact reads on the instantly claimed invention as providing a "pressure-resistant plastic casing". It should also be noted that claim 1 recites an open-ended "comprising" clause, as such WO '687 discloses the instant

invention as claimed, and the fact that it comprises an additional element (i.e., pressure resistant covering) not claimed is irrelevant.

With respect to Applicants' argument that "contrary to being pressure-resistant, the thin PEEK tubing used in FR '835, i.e., 0.65 to 0.80 mm wall thickness, is deformable by pressure. Thus, under pressure, the tubing will separate from the walls of the sorbent material creating unwanted channels ..." (Remarks, page 9, second full paragraph), the Examiner notes that the range of the "high pressure" and the thickness of the plastic tubing are absent from the instantly claimed invention, i.e., not recited in any of the claims. Further, it is believed that a suitable thickness of the sleeve for intended high pressure is either inherently disclosed, or an obvious optimization, as set forth above.

For newly added claim 18, WO '687 discloses a PTFE tubing with a pressure resistant covering, i.e., a pressure resistant PTFE tubing, as a whole, as set forth above.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/19687 as applied to claim 1 above, and further in view of Nakanishi et al. (US 5624875), substantially for the reasons set forth in section 6 of Paper No. 19, together with the following additional observations

With respect to Applicants' argument that "Nakanishi provides no motivation to modify the encasing structure of WO '687 or FR '835" (Remarks, page 10, top paragraph), the Examiner repeats (see Paper No. 12, page 4) that Nakanishi is a secondary reference, which renders obviousness to the skilled artisan at the time this

invention was made to use the inorganic porous material of Nakanishi in the chromatographic pillar of WO 94/19687, motivated by the desire to produce a chromatographic column with shorter analysis times, higher flow rates and greater reproducibility of results from multiple columns. As such, the Examiner has amply reasoned that the combined teachings of WO '687 and Nakanishi read on the instant invention of a high pressure chromatographic column.

**8. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**9.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S Chang whose telephone number is 703-605-4296. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H Morris can be reached on 703-308-2414. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

VSC

DANIEL ZINKER  
PRIMARY EXAMINER  
GROUP 1900  
1700

*Daniel Zinker*